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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/438,994	11/12/1999	JAMES J. FORT,	6487.US.01	1116
23492	7590	04/12/2006	EXAMINER	
ROBERT DEBERARDINE ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008			VENKAT, JYOTHSNA A	
			ART UNIT	PAPER NUMBER
			1615	
DATE MAILED: 04/12/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/438,994	<b>Applicant(s)</b> FORT, ET AL.	
	<b>Examiner</b> JYOTHSNA A. VENKAT Ph. D	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,13-15,18 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,13-15,18 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/30/06 has been entered.

Claims 1, 13-15, 18 and 22 are pending in the application and the status of the application is as follows:

### ***Claim Rejections - 35 USC § 103***

Claims 1, 13-15, 18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of U. S. Patents 5,545,628 ('628) and 4,769,236 ('236).

The instant application is claiming a pharmaceutical composition comprising:

1. A solid dispersion of fenofibrate or a salt or ester thereof
2. Hydroxypropylmethylcellulose (HPMC)
3. Polyethylene glycol (PEG) carrier

a method of preparing the composition and method of treating hyperlipidemia comprising administering the composition.

Patent '628 teaches pharmaceutical compositions containing fenofibrate. See col.1, lines 5-10, see col.2, lines 39-55 and see specially lines 50-51 where the patent teaches that HPMC is a suspension stabilizer which avoids the formation of fenofibrate crystals. This is same as claimed HPMC as the crystallization inhibitor. See col.2, lines 55-68, see col.3, lines 32-34,

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where the patent suggests that PEG can be incorporated into the compositions. See col.4, lines 1-30 for the preparation and packing into the hard gelatin capsules, see col.7 lines 10-15 where the patent teaches HPMC with fenofibrate. See also pharmacokinetic study. The difference between the patent and the instant application where in the patent does not teach the limitation that the solvent is ethanol. However patent '236 teaches medicaments with a high degree of solubility and method for using their preparation using crystallization inhibiting agent which is Polyvinyl pyrrolidone (PVP) in PEG using ethanol as solvent. See col.1, lines 40-68 and col.3, and see example 1 where the patent teaches ethanol as the solvent. See also claims.

Accordingly it would have been obvious to one of ordinary skill in the art to prepare fenofibrate composition taught by '628 and dissolve HPMC in PEG and use ethanol. One of ordinary skill in the art would be motivated to dissolve HPMC in PEG suggested by the patent '628 and also taught by '236 for PVP in PEG since patent '628 teaches the equivalency between HPMC and PVP as the suspension stabilizer and use ethanol with the reasonable expectation of success that high degree of solubility and dissolution of fenofibrate is obtained. This is a prima facie case of obviousness.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT Ph. D whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30:1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THURMAN K. PAGE can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**JYOTHSNA A VENKAT Ph. D**  
**Primary Examiner**  
**Art Unit 1615**

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